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EXAMINER

HASHEMI, SHAR S

ART UNIT	PAPER NUMBER
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1637

9

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,002

Applicant(s)

BARNES, WAYNE M.

Examiner

Shar Hashemi

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period of Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,6-13 and 17-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,6-13 and 17-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Amendment Changes

1. Applicant's amendment, filed on January 30, 2002 (paper No. 4) is acknowledged.

Claims 1, 2, 5, 14, 15, and 16 have been cancelled.

New claims 17-36 have been added.

Claims 3, 4, 6-13 & 17-36 are pending and being acted upon presently.

Specification

2. In the brief description of drawings, each description must correspond to a specific figure or set of figures. For example, there is no figure 1C to correspond with the description for the set of figures 1 (A-C).

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefore ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 3, 4, 6-13, 20, 22, 24, 29 & 30 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10 of prior U.S. Patent No. 5, 556, 772. This is a double patenting rejection.

Claims 1-10 of U.S. 5, 556, 772 are drawn to DNA polymerases compositions containing

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a mixture of an enzyme that lacks 3'-5' exonuclease activity and an enzyme that exhibits 3'-5' exonuclease activity. Claim 1 is drawn to a kit for the synthesis of a polypeptide comprising a first DNA polymerase where the first polymerase possesses 3'-5' exonuclease activity selected from the group consisting of *Pyrococcus furiosus* DNA polymerase, *Thermotoga maritime* DNA polymerase, *Thermococcus litoralis* DNA polymerase, and *Pyrococcus GB-D* DNA polymerase, and a second DNA polymerase where the second polymerase lacks 3'-5' exonuclease activity selected from the group consisting of *Thermus aquaticus* DNA polymerase, (exo-) *Thermococcus litoralis* DNA polymerase, (exo-) *Pyrococcus furiosus* DNA polymerase, and (exo-) *Pyrococcus GB-D* DNA polymerase. Claim 2 which is drawn to claim 1 with the further limitation of the first and second DNA polymerases are thermostable. Claim 3 is drawn to a method of amplifying a polynucleotide sequence comprise the steps of mixing a composition with a synthesis primer and a synthesis template, where the composition is made of a first DNA polymerase possessing 3'-5' exonuclease activity selected from the group consisting of *Pyrococcus furiosus* DNA polymerase, *Thermotoga maritima* DNA polymerase, *Thermococcus litoralis* DNA polymerase, and *Pyrococcus GB-D* DNA polymerase, and a second DNA polymerase lacking 3'-5' exonuclease activity selected from the group consisting of *Thermus aquaticus* DNA polymerase, (exo-) *Thermococcus litoralis* DNA polymerase, (exo-) *Pyrococcus furiosus* DNA polymerase, and (exo-) *Pyrococcus GB-D* DNA polymerase. Claim 4 which is drawn to claim 3 with the further limitation of the first and second DNA polymerases are thermostable. Claim 5 which is drawn to claim 3 with the further limitation of the first DNA polymerase is *Pyrococcus furiosus* DNA polymerase. Claim 6 which is drawn to claim 4 with the further limitation of the second DNA polymerase is *Thermus aquaticus* DNA polymerase.

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Claim 7 which is drawn to claim 5 with the further limitation of the second DNA polymerase is *Thermus aquaticus* DNA polymerase. Claim 8 which is drawn to claim 2 with the further limitation of the first DNA polymerase is *Pyrococcus furiosus* DNA polymerase. Claim 9 which is drawn to claim 2 with the further limitation of the second DNA polymerase is *Thermus aquaticus* DNA polymerase. Claim 10 which is drawn to claim 8 which is drawn to the second DNA polymerase is *Thermus aquaticus* DNA polymerase.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17-19, 21, 23, 25-28 & 31-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5, 556, 772 in view of Barnes (US 6, 410, 277 B1).

Claims 1-10 of U.S. Patent No. 5, 556, 772 have been described previously.

Claims 1-10 of U.S. Patent No. 5, 556, 772 are not drawn to *Archaeobacterial* DNA polymerase, N-terminal deleted forms of *Thermus aquaticus* DNA polymerase, KlenTaq1 DNA polymerase, Vent DNA polymerase.

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Barnes in US 6, 410, 277 B1 teach an *Archaeobacterial* DNA polymerase (col. 11, lines 27-56), N-terminal deleted forms of *Thermus aquaticus* DNA polymerase (col. 3, lines 55-62), Klentaq1 DNA polymerase (col. 3, lines 55-62), Vent DNA polymerase (col. 4, lines 17-21).

One of ordinary skill at the time the invention was made would have been motivated to apply Barnes U.S. 6, 410, 277 B1 *Archaeobacterial* DNA polymerase, N-terminal deleted forms of *Thermus aquaticus* DNA polymerase, Klentaq1 DNA polymerase, Vent DNA polymerase to Barnes' claimed method in U.S. Patent No. 5, 556, 772 of amplifying a polynucleotide sequence utilizing the steps of mixing a composition with a synthesis primer and synthesis template where the composition is made of a first DNA polymerase possessing 3'-5' exonuclease activity and a second DNA polymerase lacking 3'-5' exonuclease activity in order to efficiently catalyze the PCR amplification of unusually long and faithful products (col. 1, lines 10-16). It would have been prima facie obvious to apply Barnes U.S. 6, 410, 277 B1 *Archaeobacterial* DNA polymerase, N-terminal deleted forms of *Thermus aquaticus* DNA polymerase, Klentaq1 DNA polymerase, Vent DNA polymerase to Barnes' claimed method in U.S. Patent No. 5, 556, 772 of amplifying a polynucleotide sequence utilizing the steps of mixing a composition with a synthesis primer and synthesis template where the composition is made of a first DNA polymerase possessing 3'-5' exonuclease activity and a second DNA polymerase lacking 3'-5' exonuclease activity in order to efficiently catalyze the PCR amplification of unusually long and faithful products.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 20 & 22-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The term "comprises" renders claims 20 & 22-36 indefinite. It is unclear as to whether the first or second DNA polymerase "comprises" more than one DNA polymerase. The metes and bounds of the scope are vague.

SUMMARY

6. No claims allowed. There is no prior art that teaches or suggests a method of amplifying a polynucleotide sequence utilizing a polymerase mixture comprising a first DNA polymerase possessing 3'-5' exonuclease activity selected from the group consisting of *Pyrococcus furiosus* DNA polymerase, *Thermotoga maritima* DNA polymerase, *Thermococcus litoralis* DNA polymerase, and *Pyrococcus GB-D* DNA polymerase, and a second DNA polymerase lacking 3'-5' exonuclease activity selected from the group consisting of *Thermus aquaticus* DNA polymerase, (exo-) *Thermococcus litoralis* DNA polymerase, (exo-) *Pyrococcus furiosus* DNA polymerase, and (exo-) *Pyrococcus GB-D* DNA polymerase. The closest prior art is Scanlon (US 5, 618, 702 April 8, 1997). Scanlon teaches a method for producing a contaminating DNA free PCR amplification product utilizing a heat stable DNA polymerase. Scanlon does not teach a method for amplifying a polynucleotide sequence utilizing a polymerase mixture made of two different DNA polymerase types where the first DNA polymerase possesses 3'-5' exonuclease activity and the second DNA polymerase lacks 3'-5' exonuclease activity. Scanlon also does not teach the above mentioned two groups of DNA polymerases.

CONCLUSION

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840 and whose e-mail address is shar.hashemi@uspto.gov. However, the Office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can be best reached on weekdays from 7:00 a.m. to 3:30 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Sharon Thornton for Art Unit 1637 whose telephone number is (703)-305-3001.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-1235 and Before Final FAX (703) 872-9306 or After Final FAX (703) 308-9307.

July 10, 2002

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER

7/13/02

